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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,256	10/11/2005	Yoshihisa Naito	8721.004.US0000	1812

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EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
10/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,256	NAITO ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *11 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Rejection

Claims 1 and 3 are pending. No claim is allowed at this time. Amendments are entered.

Summary of this Office Action dated October 23, 2008

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 103 (a) Rejection
5. Declaration
6. Response to Remarks
7. Conclusion
8. Communication

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

Amendments in specification filed on 7/21/08 have been noted by the Examiner. However Applicant should file a translation of JP-A 61-233620 for consideration. The specification has not been checked to the extent necessary to determine the presence

of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3 rejected under 35 U.S.C. 103(a) as being unpatentable over GAST et al. (IDS reference). HARRISON et al (US Patent 6,572,874), WO 99266556 (abstract, IDS reference), HESSE et al. (US 5,472,957 and 3,901,928), DeLuca et al (WO 90/01321).

GAST teaches the treatment of Parturient Paresis in cows which is characterized by hypocalcaemia by treating with 1, 25-dihydroxychleclaciferol intramuscularly. See the entire document especially abstract, results and discussion. The reference does not teach transvaginal administration.

HARRISON teaches intravaginal administration of bisphosphonates into the blood circulation which improves systemic bioavailability of bisphosphonates by delivering these compounds to the circulation transvaginally ten to thirty times higher than those delivered orally. See the entire document especially lines 59-67 in column 5, lines 38-67 in column 6 and lines 1-14 in column 7.

WO 9926556 teaches an intra veginal device for delivering a pharmaceutical agent (e.g. progesterone) into a recipient mammal. The active agent is carried in matrix of a biodegradable polymer having an ability to provide desired retention characteristics of a variable geometry retention device, an appropriate release profile during a finite insertion period and biodegradability upon removal from the mammal. See the abstract.

HESSE et al teaches a method of treating osteoporosis, hypocalcaemia or bone disease by vitamin D. The reference also teaches veterinary applications of the vitamin D compounds, which includes the prevention of hypercalcaemia in domestic animals, for example farmyard animals such as cattle and sheep especially cows and ewes. See the entire document especially claim 7 and 11, abstract, lines 46-67 in column 6,

HESSE in US '928 teaches rectal administration of 1-alpha hydroxyl vitamin D compounds. See the entire document especially lines 46-54 in column 9.

DeLuca teaches the use of vitamin D compounds for the treatment of osteoporosis. See summary of invention on pages 4 and 5. See last paragraph in example 2 on page 7. The results show insignificant incidence of hypercalcaemia or other metabolic disturbance with vitamin D2 therapy. See Table 2.

Instant claims differ from the reference in method of administration of vitamin D compound, which are drawn transvaginal administration.

It would have been obvious to one skilled in the art to prepare additional beneficial compositions and for the treatment of hypercalcaemia/hypocalcemia by intra vaginal administration because the HARRISON reference teaches that systemic bioavailability of bisphosphonates **improves by delivering these compounds to the circulation transvaginally ten to thirty times higher than those delivered orally.** Since prior art teaches the uses of 1,25-dihydroxyvitamin D and it metabolic activity and the reference also teaches that improvement by transvaginal administration of drug and devices can be used to administer the drug therefore, having this knowledge at the time

of invention one skilled in the art would have been motivated to use vitamin D for vaginal use.

See KSR Supreme Court of United States Decision (Decided April 30, 2007, KSR INTERNATIONAL CO. v. TELEFLEX INC. et al. No. 04-1350) where it states that (1) "However, the issue is not whether a person skilled in the art had the motivation to combine the electronic control with an adjustable pedal assembly, but whether a person skilled in the art had the motivation to attach the electronic control to the support bracket of pedal assembly". (2) "the results of ordinary innovation are not the subject of exclusive rights under the patent laws". In KSR v. Telefex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. In KSR v. Telefex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Declaration and Response to Remarks

1. The declaration under 37 CFR 1.132 filed on 7/21/2008 is insufficient to overcome the rejection of claim based upon obviousness as set forth in the last Office action because: It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. The declaration is directed to specific concentration that is not in claims. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

2. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness..

3. International search report has not been submitted in English by the Applicants.

Applicant's arguments were fully considered but are not found persuasive because the reference does teach the advantages of using transvaginal delivery for example in WO 9926556 see page 3lines 5-9 on page 3 where it teaches that the term "intra vaginally effective active agent" means any compound or composition or complex that t means of delivery into the vaginal cavity of a mammal can be absorbed systemically by the mammal therefrom so as to achieve or suppress some physiological effect. Examples include progesterone (eg: f¢ oestrus synchronisation and other purposes) and oxytocin (eg: for milk let down)..

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612